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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,383	MAG, TED	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,31,61 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,31,61 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0802*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-44 and 71-74 in the reply filed on August 2, 2004 is acknowledged. However, the restriction requirement was made based upon the original claims and did not take into consideration the preliminary amendment filed January 22, 2002. As of that amendment, claims 1-23, 31, 61, and 72 are present for examination, and all other originally filed claims have been canceled. Therefore, the need for a restriction requirement has been obviated. Claims 1-23, 31, 61, and 72 will be examined together.

Specification

2. The use of the trademarks TriSyl®, Sorbsil®, Tonsil®, Filtrol® and Pur-Flo® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. Claims 14, 17 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 17 identify the silica and the bleach, respectively, by use of trademarks and/or tradenames. Trademarks identify the company but are not necessarily operatively linked to the contents of the composition that they name. The components and/or specific chemical nature of a trademarked composition may change but the trademark by which the composition is labeled may not change. No generic description of the claimed silica or clay is set forth in the specification. Therefore, the metes and bounds of the practice of the claimed method is not clear as one who would practice the claimed method could not be assured that he/she is using the required silica or clay composition.

Claim 31 recites refined marine mammal oil or seal oil; however, a seal is a marine mammal. The metes and bounds of the claims remain unclear, and therefore, vague and indefinite because it is unclear as to how Applicants are attempting to differentiate a seal from a marine mammal since they are one and the same.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 31 and 61 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by WO 9628150.

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003).

The term "refining" as applied to glyceride oils has been interpreted to denote "remove the gums and other impurities from the crude glyceride oils" as set forth in U.S. Patent 5,264,597 at col. 1, lines 23-26. However, the claims do not recite and therefore have not been interpreted to be limited to any degree of impurities that must be present in the marine oil to be so treated. Therefore, oils previously treated to any degree are deemed encompassed in the broadest reasonable interpretation of the oil to be used in the claimed method. Further, the process of claim 1 recites a process of refining marine oil "including" a series of steps that are further defined. However, there appears no distinction as to the order of the steps and the general rule in construing process claims is that the steps of a claim have no required order of performance unless literal language or physical constraints of the claim dictate otherwise; if a claimed step, as written, relies on composition already physically in existence, or on result of another step, then existence of those physical constraints acts as a condition precedent for said

method step. In the instant case, the only requirement for either separation step requires the previous contacting step; however, there is no requirement that either the silica-contacting step or the bleaching clay-contacting step be performed first. Therefore, broadest reasonable interpretation of the claims does not require that the silica-contacting step be performed prior to the bleaching clay-contacting step. Further, broadest reasonable interpretation of the claims permit that the contacting steps may be performed either simultaneously or concurrently, as does broadest reasonable interpretation of the claims permit the separating steps may be performed either simultaneously or concurrently.

Finally, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). "The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims

because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

The prior art document WO 96/28150 teaches a refined seal oil to be used in a composition to be used therapeutically on the skin. The reference also teaches that seal oil has been used nutritionally. As discussed above, the product produced by the method of claim 1 is refined seal oil, i.e. one that has had impurities removed. Since the interpretation is to be applied in the same manner to the use of the term in the prior art, the seal oil of the reference has had impurities removed and therefore anticipates the cited product claim. The use of the same product in a medical treatment that uses an effective amount of the same product equally anticipates the cited method claim.

6. Claims 1-4, 6-7, 10, 12-13, 15-20, 31 and 72 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent 5,336,794 to Pryor et al.

Pryor et al. teach a dual phase adsorption treatment for glyceride oils. At col. 1, lines 30-35, glyceride oils are defined as <u>any</u> vegetable or animal oil, including edible oils from animal fats chiefly used in foodstuffs. A simple dual phase adsorption and treatment process is taught for the removal of impurities in either chemically or physically refined glyceride oils. Physically refined glyceride oils are ones that have not

undergone a caustic refining step, usually the addition of caustic alkali to the oil to neutralize the free fatty acids and convert them to soaps. These soaps are then removed. The dual phase adsorption process begins with contacting the oil with amorphous silica adsorbents to remove all or substantially all soaps, gums or both from the oil and reduce the phospholipid content of the oil. At col. 7, silica adsorbents are defined to include silica gels, and silica gels of the brand TriSyl® are used in preferred embodiments. Silica gel is mixed with the oil followed by a filtration treatment to remove the spent silica gel. The preferred amount of amorphous silica is at least about 0.01 to about 1.0 wt % of the oil to be processed (claim 13). See col. 11, lines 30-36.

Following the silica treatment, the oil is filtered through a packed bed of pigment removal agent, which is defined as bleaching clay. The preferred amount of the bleaching clay is defined as about 0.01 to about 1.0 wt % of the oil. See col. 12, lines 30-35 (claim 16). The oil is also heated during the bleaching treatment to heats of about 90°C to about 120°C but may go as high at 150°C (see col. 12, lines 45-50 (claim 18)).

The cited claim limitations are therefore anticipated by the cited reference. Non-disclosed limitations of the cited claims are deemed inherent in the disclosure of the reference, particularly the requirements to the specific oils from marine mammals or fish since the prior patent teaches that any oil from any animal fat may be treated in the claimed manner. Therefore, the prior patent inherently teaches all animal oils including marine fish and mammals. With regard to the limitations of claim 2, since a physical refining process can precede the disclosed dual phase process, such a process would

not use a caustic alkali treatment nor require an acid treatment. With regard to the use of the phrase "consisting of" in claim 3, since Applicant defines the term "marine oil", per claim 72, as encompassing both crude and foundation oil, the physically or chemically refined oil used in the dual adsorption method fall within broadest reasonable interpretation of this term and since no other treatment is required to be performed after the dual adsorption treatment, the disclosure is deemed to anticipate this claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,336,794 to Pryor et al. in view of U.S. Patent 5,069,829 or U.S. Patent 5,264,597 to Van Dalen et al. and U.S. Patent 5,855,944 to Koschinski et al.

The disclosure of U.S. Patent 5,336,794 to Pryor et al. is discussed supra. U.S. Patents to Van Dalen et al. teaches that conventional crude glycerol oil refinement includes a degumming step, conventionally performed with water, to remove phosphatides. A subsequent acid and/or alkali treatment is often performed to remove phosphatides and convert free fatty acids to soaps for later removal. Subsequent treatment then includes a bleaching (a.k.a. decolorizing) step and deodorization step.

Van Dalen et al. teach that it may be possible to avoid the alkali refining step all together, which is described as physical refining and "is highly desirable in terms of processing simplicity and yield." Therefore, Van Dalen et al. provides a motivation for the practitioner not to engage in an alkali and/or acid treatment step of glyceride oils. Van Dalen et al. also teaches that water degummed glyceride oils may be contacted with a silica hydrogel, the water is removed and the silica hydrogel is separated, to produce a glyceride oil with phosphatides and other impurities removed. After refining with silica hydrogel, the refined oil may be further refined using bleaching earth (clay) TriSyl® is taught as an appropriate silica gel and deodorization is taught at temperatures of 240°C.

Finally, U.S. Patent 5,855,944 to Koschinski et al. teaches that partially refined marine oils that have been bleached may be treated with silica gels in a vacuum within the limits claimed and may also be subjected to an additional deodorization step. Columns or batch reactors are contemplated. The resultant refined oils are incorporated into conventional composition such as foodstuffs or dietary supplements.

It would have been obvious to one of ordinary skill in the art to encompass conventional silica gel adsorbent steps in the process of refining marine animal oil and specifically marine fish or mammalian oil without an alkali and/or acid step because Van Dalen et al. teach that such is preferred. Such a motivation is supported by the prior patent to Pryor et al. that teaches that physical refining steps may be alternatives to chemical refining (caustic alkali) steps. The processes recited in the claims all use conventional and known materials in conventional manners and at known levels, times

and temperatures. The resultant oils and their known uses are also conventional as indicated by the cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1651